

REMARKS

Claims 61-73, 80-89, and 95-100 are pending. Claims 61 and 72 were amended as suggested by the Examiner at page 2 of the Office Action to use “consisting of” language in the method and to expressly exclude emulsification means, a vortexing step or a stirring step from the evaporation step in the method. The amended claims more specifically indicate that the method for the preparation of microparticles is from a one-phase system by evaporation. The amendment is supported by the original claims and Example 1. Accordingly, no question of new matter arises and entry of the amendment is requested, respectfully.

Claims 62-68 have been amended to recite proper antecedent basis and, therefore, the amendments are not meant to limit the scope of these claims. Claim 71 was amended to prevent dependency from a canceled claim and claim 68 was amended to insert a word inadvertently omitted. These amendments also are not intended to limit the scope of the claims.

Claim Rejections - 35 U.S.C. § 112

From pages 2-4 of the Office Action, claims 61-100 were rejected under 35 U.S.C. § 112, first paragraph. The Examiner asserted that the specification is enabling for a less broad method and composition.

The method and composition claims have been amended to incorporate the Examiner’s suggested language from page 2 of the Office Action. Accordingly, the rejection is overcome and should be removed.

Claim Rejections - 35 U.S.C. § 112, second paragraph

From pages 4-5 of the Office Action, claims 61-100 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. The Examiner asserted that the claims were broader than Applicant's own interpretation of the invention.

The amended claims now more clearly recite Applicant's own interpretation of the invention.

Accordingly, the rejection is overcome and should be removed.

Claim Rejections - 35 U.S.C. § 102

From pages 5-8 of the Office Action, claims 61-100 were rejected under 35 U.S.C. § 102(b) as being anticipated by any of Woiszvillo (U.S. Patent 5,849,884), OctoPlus (EP 0 842 657), or Magnus (EP 0 213 303). The Examiner asserted that the claim language was so broad as to embrace the method recited in the references.

For the following reasons, the rejection is overcome.

Woiszvillo describes a method for the formation of microparticles by mixing macromolecules in solution or a liquid phase with a polymer or mixture of polymers in solution or liquid phase in the presence of an energy source (col. 7, lines 5 to 9). The energy source can either be heat, radiation, or ionization, alone or in combination with sonication, vortexing, mixing or stirring for a predetermined length of time (col. 7, lines 33-37). Moreover, Woiszvillo refers to a number of different techniques routinely used to provide microparticles from synthetic polymers, natural polymers, proteins and polysaccharides, including phase separation, solvent evaporation, emulsification, and spray drying (col. 1, lines 40 to 44). Thus, solvent evaporation is mentioned in a general broad context without the specification of its functional advantages.

Since one skilled in the art knows from all the examples of Woiszvillo that the phase separation is initiated by vortexing or stirring, he understands that according to Woiszvillo the evaporation has a mere supportive function to concentrate or solidify the microparticles once they are formed. The evaporation thus is not disclosed as an instrument to form a dispersed and continuous phase.

In contrast to this, the method according to the invention is based on the usage of evaporation in order to achieve a dispersion (and thus microparticles).

The claims have been amended to expressly exclude emulsification means, a vortexing step or a stirring step in the evaporating step. Accordingly, Woiszvillo does not anticipate the claims.

OctoPlus relates to an aqueous two-phase system with crosslinkable polymers, wherein a crosslinkable polymer phase is emulsified in the other aqueous polymer phase to form microspheres.

Thus, the formation of microparticles is based on the formation of crosslinks between polymers.

Claim 61 has been amended to use “consisting of” language, thereby excluding the formation of crosslinks between polymers. Accordingly, the presently claimed invention is not anticipated by OctoPlus.

Magnus describes a method for producing polymer particles from a two-phase emulsion system. The microparticles are solidified by input of energy to the two-phase system via evaporation.

Therefore, evaporation as used in Magnus is applied as a concentration step for the solidification of the particles and not for the formation of microparticles as described in the present invention. The subject-matter of the present invention is therefore novel over Magnus.

Claim 61 has been amended to clearly indicate that the microparticles are formed from evaporation. Accordingly, Magnus does not anticipate the present claims.

In view of the above remarks, the Examiner is respectfully requested to reconsider and remove the rejection.

Claim Rejections - 35 U.S.C. § 102(a)

From page 8 to page 9 of the Office Action, composition claims 72-100 were rejected under 35 U.S.C. § 103(a) as being unpatentable over OctoPlus (EP 0 842 657), or Magnus (EP 0 213 303), each of which taken with Carli (U.S. Patent 6,355,273), Mathiowitz (U.S. Patent 6,745,779 B2), Burke (U.S. Patent 6,183,781) or Gombotz (U.S. Patent 6,274,175). The Examiner cited OctoPlus and Magnus for the reasons stated in the rejection under 35 U.S.C. § 102. To the extent that these references do not disclose the limitations of the dependent claims, the Examiner cited Carli, Mathiowitz, Burke, and Gombotz.

For the reasons discussed above with respect to the anticipation rejection, the cited primary references do not anticipate or make obvious the independent claims. Furthermore, none of the secondary references teaches formation of particles from evaporation. Accordingly, the secondary references do not fill the deficiencies needed to find the dependent claims obvious.

In view of the above, the Examiner is respectfully requested to reconsider and remove the rejection.

AMENDMENT UNDER 37 C.F.R. § 1.114
U.S. Appln. No. 10/018,773

Q67842

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER



Susan J. Mack
Registration No. 30,951

DREW HISSON

44,765

Date: June 23, 2004